K092193

510 (k) Summary of Safety and Effectiveness

SEP 25 2009

Date Summary Prepared: July 17, 2009

Submitter Information: Spinal USA
2050 Executive Drive
Pearl, MS 39208

Contact Name: Jeffrey Johnson
Phone: 601-420-4244
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E-mail: jeff@spinalusa.com

Device Trade Name: Spinal USA Intervertebral Body Fusion Device

Common Name: Intervertebral Body Fusion Device

Product Code: MAX (Class II) 888.3080
KWQ (Class II) 888.3060

Basis for Submission: Modification to components
Additional components

Predicate Device: Spinal USA Interbody Fusion Device (K081196)
Spinal USA Interbody Fusion Device (K080314)

INTENDED USE: The Spinal USA Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space for the ALIF, LLIF, TLIF and T-PLIF system. Two devices are used per intervertebral space for the PLIF system.

The Spinal USA Interbody Fusion Device ALIF, LLIF, TLIF, T-PLIF and PLIF System are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with supplemental fixation and autogenous bone graft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

The Spinal USA Interbody Device Stabilizer RPIF System is intended to be used only in anterior procedures in which an ALIF device of the same height is implanted. The Stabilizer RPIF device is not meant for stand alone use.

DEVICE DESCRIPTION: The Spinal USA Interbody Fusion Device consists of implants with various widths, heights, lengths and bone screws to accommodate individual patient anatomy and graft material size. All components are manufactured from Ti-6Al-4V titanium alloy (ASTM F136) or medical grade polyetheretherketone (Peek LT1). The products are supplied clean and "NON-STERILE".

EQUIVALENT DEVICE: Documentation was provided which demonstrated the Spinal USA Interbody Fusion Device to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in intended use, indications, anatomic sites, performance and material of manufacture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Spinal USA
% Mr. Jeffrey Johnson
Manager, Regulatory Affairs
2050 Executive Drive
Pearl, Mississippi 39208

SEP 25 2009

Re: K092193
Trade/Device Name: Interbody fusion device
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervetebral body fixation orthosis
Regulatory Class: II
Product Code: MAX, KWQ
Dated: September 1, 2009
Received: September 1, 2009

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buehrn for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092193

Device Name: Interbody Fusion Device

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen B. Burns for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092193